510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k052882

B. Purpose for Submission:

Pre-market clearance of a new device

C. Measurand:

Amphetamine, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine, Methamphetamine, Methadone, Opiates (2000), Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressant (TCA)

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Tianjin New Bay Bioresearch

F. Proprietary and Established Names:

Forsure Rapid One Step Multiple (X) Abuse Drug Screen Test Cup device

G. Regulatory Information:

1. Regulation section:
   862.3100, Amphetamine Test System
   862.3150, Barbiturate Test System
   862.3170, Benzodiazepine Test System
   862.3870, Cannabinoids Test System
   862.3250, Cocaine and Cocaine Metabolite Test System
   862.3620, Methadone Test System
   862.3610, Methamphetamine Test System
   862.3650, Opiates (2000) and Oxycodone Test System
   Unclassified, Enzyme Immunoassay, Phencyclidine
   862.3700, Propoxyphene Test System
   862.3910, Tricyclic Antidepressant Drugs Test System

2. Classification:

   Class II

3. Product code:

   DKZ, DIS, JXM, LDJ, DIO, DJC, DJR, DJG, LCM, JXN, LFH, respectively

4. Panel:

   91, Toxicology

H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

   The Forsure Rapid One Step Multiple (X) Abuse Drug Screen Test Cup Device is for the detection of Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Cannabinoid, Morphine, Phencyclidine, Methadone, Oxycodone, Tricyclic Antidepressant (TCA), Barbiturates and Propoxyphene and their metabolites in human urine at the following cutoff concentrations:

Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturate	Secobarbital	300 ng/mL
Benzodiazepine	Oxazepam	300 ng/mL
Cannabinoid	THC-COOH	50 ng/mL
Cocaine	Benzoylecgonine	300 ng/mL
Methamphetamine	(+) Methamphetamine	1000 ng/mL
Methadone	(+/-) Methadone Hydrochloride	300 ng/mL
Opiates	Morphine	2000 ng/mL
Oxycodone	Oxycodone Hydrochloride	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Propoxyphene	(+) Propoxyphene	300 ng/mL
Tricyclic Antidepressant	Nortriptyline Hydrochloride	1000 ng/mL

   The assay provides only preliminary analytical test results. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. The testing and results are intended to be used by medical professional.

3. Special conditions for use statement(s):

   For Prescription use only

4. Special instrument requirements:

   Not applicable, as the device is a visually-read single-use device.

I. Device Description:

The Forsure Rapid One Step Multiple (X) Abuse Drug Screen Test Cup Device and holder are designed to hold one or up to twelve individual chromatographic absorbent strips in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. The method employs unique monoclonal and polyclonal antibodies to selectively identify the drug or drug metabolite in the sample. The membrane on the strip is coated with goat anti-mouse antibody and a specific drug-protein conjugate. The sample pad contains a colloidal gold labeled mouse monoclonal anti specific drug antibody. The device is for single-use and visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Branan Medical Corporation; Monitect multiple Drug screen cassette test

   ALFA Scientific Designs INC.; Instant-View Propoxyphene Urine test

2. Predicate 510(k) number(s):

   k004034 and k022915, respectively

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Qualitative determination of drugs in human urine	Qualitative determination of drugs in human urine
Matrix	Human Urine	Human Urine
Test Principle	Immunochromatographic, lateral flow	Immunochromatographic, lateral flow

Differences		
Item	Device	Predicate
Device	Test cup	Cassette

K. Standard/Guidance Document Referenced (if applicable):

Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Program, Fed Register. 53(69): 11970-11979, 1988

Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA) research Monograph 73, 1986

L. Test Principle:

The Forsure Rapid One Step Multiple (X) Abuse Drug Screen Test Cup Device and holder are designed to hold one or up to twelve individual chromatographic absorbent strips in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the sample flows through the absorbent device by chromatography, the labeled antibody-Gold sol conjugate binds to the free drug in the sample forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the test zone. If the concentration of drug is above the cutoff concentration no magenta colored band will form, indicating a positive result. If the concentration of drug in the sample is below the cutoff, a magenta colored band will form, indicating a negative result. Unbound dye conjugate binds to the reagent in the control zone, producing a magenta colored band, regardless of the presence or absence of drug or drug metabolite in the urine sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed using in house drug standards. The standard was diluted in drug-free urine to give drug concentrations at the following levels: 0, 50%, 75%, 100%, 125% and 150% of the cutoff. A total of 15 determinations were made at each concentration for each analyte. Testing was performed on one day by one operator. All samples at 0 and -50% yielded negative results and all samples 150% yielded positive results. Within lot precision study data for 75%, 100%and 125% is summarized below:

75% of Cutoff

	AMP	BAR	BZD	COC	MET	MTD	OPI 2000	OXY	PCP	PPX	TCA	THC
Total # determinations	15	15	15	15	15	15	15	15	15	15	15	15
Concentration (ng/mL)	750	225	225	225	750	225	1500	75	18.75	225	750	37.5
#NEG/#POS	14/1	15/0	13/2	14/1	13/2	13/2	14/1	12/3	13/2	10/5	11/4	14/1
Precision	93%	100%	87%	93%	87%	87%	93%	80%	87%	67%	73%	93%

100% of Cutoff

	AMP	BAR	BZD	COC	MET	MTD	OPI 2000	OXY	PCP	PPX	TCA	THC
Total # determinations	15	15	15	15	15	15	15	15	15	15	15	15
Concentration (ng/mL)	1000	300	300	300	1000	300	2000	100	25	300	1000	50
#NEG/#POS	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15
Precision	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

125% of Cutoff

	AMP	BAR	BZD	COC	MET	MTD	OPI 2000	OXY	PCP	PPX	TCA	THC
Total # determinations	15	15	15	15	15	15	15	15	15	15	15	15
Concentration (ng/mL)	1250	375	375	375	1250	375	2500	125	31.25	375	1250	62.5
#NEG/#POS	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15
Precision	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Inter Lot precision:

To test inter lot precision, drug-free urine was spiked with commercially available drug standard to the following levels: 0, 50%, 75%, 100%, 125% and 150% of cutoff. Testing was performed using three different lot numbers, 15 samples of each lot were run at each of the concentrations for each drug over 20 days. All samples tested at 0, -50% yielded negative results and all samples at 150% yielded positive results. Inter lot Precision Study data for 75%, 100% and 125% of cutoff is summarized below:

75% Cutoff	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Precision
AMP	15	15	15	14/1	13/2	13/2	93%	87%	87%	89%
BAR	15	15	15	14/1	13/2	14/1	93%	87%	93%	91%
BZD	15	15	15	12/3	13/2	11/4	80%	87%	73%	80%
COC	15	15	15	13/2	14/1	14/1	87%	93%	93%	91%
MET	15	15	15	11/4	14/1	11/4	73%	93%	73%	80%
MTD	15	15	15	14/1	14/1	13/2	93%	93%	87%	91%
OPI 2000	15	15	15	14/1	12/3	12/3	93%	80%	80%	84%
OXY	15	15	15	11/4	11/4	12/3	73%	73%	80%	75%
PCP	15	15	15	14/1	14/1	13/2	93%	93%	87%	91%
PPX	15	15	15	11/4	10/5	11/4	73%	67%	73%	71%
TCA	15	15	15	13/2	11/4	12/3	87%	73%	80%	80%
THC	15	15	15	13/2	14/1	14/1	87%	93%	93%	91%

100% Cutoff	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Precision
AMP	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BAR	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BZD	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
COC	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MET	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MTD	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
OPI 2000	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
OXY	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
PCP	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
PPX	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
TCA	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
THC	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%

125% Cutoff	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Precision
AMP	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BAR	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BZD	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
COC	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MET	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MTD	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
OPI 2000	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
OXY	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
PCP	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
PPX	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
TCA	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
THC	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%

b. Linearity/assay reportable range:
Not applicable. The assay is intended for qualitative use.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Procedural controls are included in the test strip and device. A magenta line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External control materials are not supplied with these tests; however it is recommended that positive and negative controls be tested as a good

laboratory practice to confirm the test procedure and to verify proper test performance. User should follow local, state and federal guidelines for testing QC material.

Stability:

Real time and accelerated studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date:

When stored at 15 – 28 ºC product is good until expiration date which is 18 months.

Storage of sample:

To determine if there was any effect on the specimen from prolonged exposure to the device the following study was performed. An in-house positive urine control containing drug for each analyte in the test device was tested on the Chromatograph Mass Spectrometry GC/MS to obtain an initial value. The sample was then aliquot into the test device and moderately shaken for 10 minutes, then stored at room temperature (15-30 ºC) for total of 60 hours. Samples for GC/MS analysis were taken at times 0, 12, 36 and 60 hours. The results demonstrate that the test device did not affect the expected or accuracy of the results.

d. Detection limit:

A drug-free urine pool was spiked with specific drug at the following concentrations: 25% and 50% below the cutoff, cutoff and 25% above the cutoff. The results are presented in the table below:

	AMP	BAR	BZD	COC	MET	MTD	OPI 2000	OXY	PCP	PPX	TCA	THC
Total # determinations	15	15	15	15	15	15	15	15	15	15	15	15
-50% of cutoff/ concentration ng/mL	500	150	150	150	500	150	1000	50	12.5	150	500	25
#NEG/#POS	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0
-25% of cutoff/ concentration ng/mL	750	225	225	225	750	225	1500	75	18.75	225	750	37.5
#NEG/#POS	11/4	12/3	11/4	11/4	11/4	9/6	12/3	11/4	10/5	10/5	13/2	10/5
Cutoff/ concentration ng/mL	1000	300	300	300	1000	300	2000	100	25	300	1000	50

#NEG/#POS	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15
+25% of cutoff/ concentration ng/mL	1250	375	375	375	1250	375	2500	125	31.25	375	1250	62.5
#NEG/#POS	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into normal human urine. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the tables below:

Amphetamine

Drug Compound	Response equivalent to cutoff in ng/mL
d-amphetamine	1000
d,l-amphetamine	10,000
l-amphetamine	25,000
B-Phenylethylamine	180,000
d-Methamphetamine	400,000
l-Methamphetamine	400,000
(±)3,4-Methylenedioxy-methylamphetamine-HCL-(±) 3,4 MDMA-HCL	400,000
3,4-Methylenedioxyamphetamine (MDA)	1200
Tyramin	100,000

Methamphetamine

Drug Compound	Response equivalent to cutoff in ng/mL
(+)methamphetamine	1000
d,l-Amphetamine Sulfate	200,000
l-Amphetamine Sulfate	200,000
(±) 3,4 – Methylenedioxy-amphetamine-HCL (±) 3,4 MDA-HCL	200,000
d-Amphetamine Sulfate	200,000
3,4-Methylenedioxymethamphetamine (MDMA)	1000

Opiates 2000

Drug compound	Response equivalent to cutoff in ng/mL
Opiate	2000
Codeine	2,000
Heroin	2000
Levorphanol	4000
Ranitidine	100,000
Morphine-3-β-D glucuronide	2,000
6-Acetylmorphine	50

Cocaine

Compound	Response equivalent to cutoff in ng/mL
Benzoylecgonine	300
Cocaine	300

Cannabinoids (THC)

Compound	Response equivalent to cutoff in ng/mL
Cannabinol	10,000
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	50
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	50
Δ^8-Tetrahydrocannabinol	7500
Δ^9 –Tetrahydrocannabinol	10,000
11-hydroxy-Δ^9 –Tetrahydrocannabinol	2500

Phencyclidine

Compound	Response equivalent to cutoff in ng/mL
Tenocyclidine	2000
Phencyclidine	25

Barbiturates

Compound	Response equivalent to cutoff in ng/mL
Secobarbital	300
Allobarbital	600
Amobarbital	600
Barbital	300
Butabarbital	300
Butalbital	300
Pentobarbital	300
Phenobarbital	300

Benzodiazepines

Compound	Response equivalent to cutoff in ng/mL
Alprazolam	600
Chlordiazepoxide	300
Diazepam	300
Oxazepam	300
Clonazepam	300
Flunitrazepam	300
Nitrazepam	250
Bromazepam	100
Clobazam	300
Estazolam	300
Flurazepam	150
Lorazepam	500
Lormetazepam	500
Clorazepate	200
Nordiazepam	150
Prazepam	1500
Temazepam	150
Delorazepam	3000
Triazolam	200

Methadone

Compound	Response equivalent to cutoff in ng/mL
Methadone	300
Doxylamine	50,000
(±)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	100,000
Methadol	25,000
Perphenazine	75,000
Protriptyline	2000
Trimipramine	10,000

Propoxyphene

Compound	Response equivalent to cutoff in ng/mL
Propoxyphene	300
Norpropoxphene	1000
Methadone	1,350,000
2-ethyl-1,5-dimethyl 3,3-diphenylpyrroline	200,000

Oxycodone

Compound	Response equivalent to cutoff in ng/mL
Oxycodone-HCL	100
Morphine-Sulfate	7000
Codeine	700
Morphine 3-β-D glucuronide	40,000
Hydromorphone	1500
Norcodeine	40,000
Oxymorphone	300
Hydrocodone	500

Tricyclic Antidepressant (TCA)

Compound	Response equivalent to cutoff in ng/mL
Amitriptyline	1000
Cyclobenzaprine	1500
Clomipramine	5000
Desipramine	600
Doxepin	1000
Imipramine	600
Nortriptyline	1000
Nordoxepin	1000

The following list of substances showed no interference at a concentration of 100 ug/mL in urine:

Common Substances:

Acetaminophen	Diphenhydramine	(+/-) Naproxen
Acetone	5,5-Diphenylhydantoin	Nicotine
Acetylsalicylic Acid	Dopamine	Nor-Bupreorphine
Amikacin	EDDP	Noscapine Hydrochloride
Amitriptyline	+ Ephedrine	Oxalic Acid
Ampicillin	- Ephedrine	Omega-3-fatty acid
l-Ascorbic Acid	+/- Epinephrine	Penicillin-G
Aspartame	Erythromycin	Phenalzine
Aspirin	Ethanol	l-Phenylephrine
Atropine	Fentanyl	(+/-) Phenylpropanolamine
Benzocaine	Fluoxetine	Promathazine
Benzoic Acid	Furosemide	Pseudoephedrine
Buprenophine-3-β-D-glucuronide	Glucosamine	Quinine
(+)-Brompheniramine	Guaiacol Glyceryl Ether	Quinidine

Buprenorphine	Hydrochlorothiazide	Salicylic Acid
Caffeine	Hydrocodone	Sustiva
(+)-Chlorpheniramine	Ibuprofen	Sulindac
(+/-)- Chlorpheniramine	Ketamine	Theophyline
Chlorpromazine	Lidocaine	Thioridazine
Cortisone	Maprotiline	Tramandol
(-)-Cotinin	Meperidine	d(+)-Trehalose
Creatinine	Methanol	Trifluoperazine
Dextromethorphan	Methylphenidate	
4-Dimethylaminoantipyrine	Naltrexone	

The following list of substances showed no interference at the following concentrations in either drug-free or drug positive urines:

Bilirubin	0.2 -1.0 mg/dL
Creatinine	500 mg/dL
Glucose	1500 mg/dL
Hemoglobin	300 mg/dL
Potassium	10-110 mEq/dL
Human Serum Albumin	500 mg/dL
Globulin	1500 mg/dL
Sodium chloride	0-6000 mg/dL
Uric Acid	23 mg/dL
Cholesterol	500 mg/dL

Specific Gravity:

Two drug free urines, one with a specific gravity of 1.030 and the other 1.003. The sample was divided into two and one was spiked with drug concentration at 25% above the cutoff for all the analytes. Each sample was run in duplicate. The results demonstrate that a specific gravity range of 1.003 – 1.030 did not affect the expected or accuracy of the results.

pH:

The pH of an aliquot negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH increments for a total of six samples. Each of the samples was split into two samples to form a pair for each pH level. One of the paired samples from each set was spiked with drug concentration at 25% above the cutoff for all the analytes. Each sample was run on the device and the results demonstrate that varying ranges of pH dose not interfere with the performance of the test.

f. Assay cut-off:

The identified cutoff concentrations for amphetamine, cocaine, methamphetamine, opiates 2000, Phencyclidine and THC are those recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA). The SAMHSA has not recommended a cutoff concentration for Barbiturate, Benzodiazepine, Oxycodone, Propoxyphene and Tricyclic Antidepressant (TCA).

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision and detection limit sections, above.

2. Comparison studies:

a. Method comparison with predicate device:

83-110 urine samples, depending on the drug type were evaluated. Specimens obtained from a reference laboratory were tested using the Forsure Rapid One Step Multiple (X) Abuse Drug Screen Test Cup Device and the Gas Chromatography/Mass Spectrometry (GC/MS). For each tested, approximately 10% of samples had drug concentration between 50% below the cutoff and the cutoff concentration, another 10% of samples had drug concentration between the cutoff and 50% above the cutoff concentration.

Candidate Device Results vs. stratified GC/MS Values

	Candidate Device Results	**Negative** by the predicate device or less than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)	**% Agreement** (among positives and negatives)
AMP	Positive	0	4	5	42	100%
	Negative	58	1	0	0	94%
BAR	Positive	0	2	19	20	100%
	Negative	49	3	0	0	96%
BZD	Positive	0	4	14	28	100%
	Negative	49	2	0	0	93%
COC	Positive	0	2	14	28	100%
	Negative	49	3	0	0	93%
MET	Positive	0	0	10	31	100%
	Negative	50	5	0	0	100%
MTD	Positive	0	4	8	33	100%
	Negative	62	1	0	0	94%
OPI 2000	Positive	0	0	17	24	100%
	Negative	50	5	0	0	100%
OXY	Positive	0	1	5	50	100%
	Negative	40	3	0	0	98%
PCP	Positive	0	4	16	25	100%
	Negative	50	3	0	0	93%
PPX	Positive	0	3	19	24	100%
	Negative	50	2	0	0	95%
TCA	Positive	0	1	18	13	100%
	Negative	38	4	0	0	98%
THC	Positive	0	1	6	36	100%
	Negative	50	3	0	0	98%

During the accuracy for Amphetamine and Methamphetamine testing one discordant result was observed. A sample was run for both analytes, during the Amphetamine testing the PCP was recorded as positive and in the Methamphetamine the PCP was recorded as negative. The results were not confirmed by a reference method.

During the accuracy of the other analytes there were positive results recorded for analytes other then the one being tested. None of the other results were confirmed by a reference method.

b. Matrix comparison:

Not applicable. This device is only for use with urine sample.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable. Clinical studies are not typically submitted for this device type.

b. Clinical specificity:

Not applicable. Clinical studies are not typically submitted for this device type.

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.